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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,944	10/31/2000	Hiroshi Fukuda	20498	1795

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EXAMINER

MORRIS, PATRICIA L

ART UNIT PAPER NUMBER

1625

DATE MAILED: 03/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/702,944

Applicant(s)  
Fukuda et al.

Examiner  
Patricia L. Morris

Art Unit  
1625



-- The MAILING DATE of this communication appears n th cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 12, 19-21, 25, 28, and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-18, 22-24, 26, 27, 30, and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2-4 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-11, 13-18, 22-24, 26, 27, 30 and 31 are under consideration in this application.

Claims 12, 19-21, 25, 28 and 29 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

### ***Election/Restriction***

Applicant's election of Group I and the species of example 7 in Paper No. 6, filed January 14, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

This application has been examined with regard to the elected compound wherein Q represents (2R,3R)-3-[4-(4-cyanophenyl)thiazol-2-yl]-2-(2,5-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-butan-2-ol, R<sup>3</sup> is (optionally substituted) pyridin-2-yl and R<sup>1</sup>, R<sup>2</sup> and X as set forth in claim 1, exclusively.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-11, 13-18, 22-24, 26, 27, 30 and 31 are rejected under 35 U.S.C. 102(a), (e) and/or (f) as being anticipated by Hayase et al. (US 6,300,353).

Hayase et al. specifically recite the compound (2R,3R)-3-[4-(4-cyanophenyl)thiazol-2-yl]-2,5-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-butan-2-ol. Note column 5, lines 5-6, therein.

The precursor and final product are not different products, regardless of differences in their activity and efficacy. See *Marion Merrell Dow Inc v. American Cyanamid Co.*, 36 USPQ2d 1036. Hence, the instant compound is deemed to be anticipated therefrom.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13-18, 22-24, 26, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayase et al. in view of Hudyma et al. (US 6,265,584) and Davidsen et al., (J. Med. Chem., 37 (26) 1994 pgs.4423-4429).

Hayase et al. disclose the final product having the same use. Note compound no. 43 therein. Hudyma et al. teach that analogous amine salts of triazoles similar to those of the claimed invention retained the activity associated with the final products, whereas Davidsen teach that pyridine salts are known to be extremely soluble. In view of the structural similarity between the compounds of the instant claims and those of Hayase et al. and that the substituent connected with the differentiating feature is lost *in vivo*, one of ordinary skill in the art would expect that the claimed compounds would have antifungal activity. It is well settled that the final product and its precursor are not different products, regardless of differences in their activity and efficacy. *Marion Merrell Dow Inc. V. American Cyanamid Co.*, supra.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expressions “optionally substituted,” “solvates” and “derivative with antifungal .....azole” in claims 1 and 2 are employed with considerable abandon throughout the claims with no indication given as to what the substituents, solvates and derivatives really are. What is meant by the term derivative?

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

Applicant has been permitted the examination of their pharmaceutical use here, as well. In the pharmaceutical area, declarations under 37 CFR 1.132 are often employed to set forth the advantage of a particular substituent or group. The definition and claiming of the substituents

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and groups is extremely important in the claims of the application. Applicant should not be able to preempt future work of others by means of claims to compounds that he did not make.

The written description is considered inadequate here in the specification. Conception of the intended substituents and aryl groups should not be the role of the reader. Applicant should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first and second paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co., 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. v. United States, 193 USPQ 449, "Claims measure invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 USPQ 11, at 15.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-11, 13-18, 22-24, 26 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The plural 's' on "salts, hydrates, solvates and compounds" makes claims 1-11, 13-18, 22-24, and 26 read on mixtures rather than specific compounds. Also, the phrase "as well as... formula (I)" is not written in alternative language. The phrase "or a pharmaceutically acceptable salt.... formula(I)": - is suggested.

Regarding claim 30, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

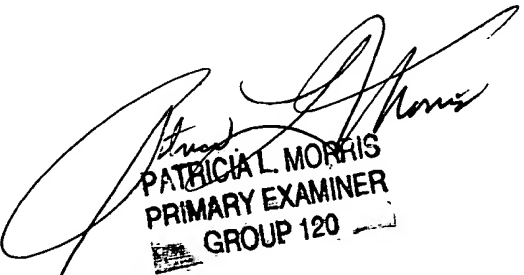
### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

February 15, 2002

  
PATRICIA L. MORRIS  
PRIMARY EXAMINER  
GROUP 120